APR 15 2005

510(k) Number: K041495

510(k) SUMMARY
(As Required by 21 CFR 807. 92)

Submitted by: **Dr. Vittorio Servidori**
General Manager
PENTAFERTE S.p.A
Loc. Nocella Statale 262
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Date of Summary: March 23, 2003

Device Name: PENTADEFLU IV Administration Sets

Common Name: Intra Vascular Administration Set

Classification Name: Intra Vascular Administration Set

Class: 2

Product Code: FPA

Regulation Number: 21 CFR 880. 5440

Predicative Device: Victus IV Administration Sets (K023469)

Modifications: There are no modifications to the device design that affect safety and effectiveness of the PENTADEFLU IV Administration Sets

Device Description The PENTADEFLU IV Administration Sets are Single Use, Sterile, Non-Pyrogenic devices used to administer IV fluids/medications to a patient's vascular system via gravity control.

Intended Use: To Administer IV Fluids/medications to the patient's vascular system.

Technological The PENTADEFLU IV Administration Sets have the same technological characteristics as the legally marketed predicative IV Administration Sets.

Testing: The PENTADEFLU IV Administration Sets have been subjected to performance and safety testing to verify mechanical properties and functioning, as well as biocompatibility and sterility, using FDA recognized Standards, where applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

PENTAFERTE S.p.A
C/O Mr. Victor Pereira
Consultant
7410 NW 65th Lane
Parkland, Florida 33067

Re: K041495
Trade/Device Name: PENTADEFLU™ IV Administration Sets
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 29, 2005
Received: April 6, 2005

Dear Mr. Pereira:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number K041495

Device Name: PENTADEFLU™ IV Administration Sets

INDICATIONS FOR USE: To administer IV Fluids into a patient's vascular system

Prescription Use: X
9part 21 CFR 801 Subpart D)

AND/OR

Over-the counter Use;_____
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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